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A Comparative Analysis of Regulatory Requirements for Nutraceuticals and Dietary Supplements across Major Markets

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Abstract:

This study undertook a comparative regulatory analysis of nutraceuticals and dietary supplements across eight major markets: United States, European Union, Canada, Australia, India, Japan, China, and Brazil. Through systematic review of legal texts, guidance documents, and regulator portals, the research mapped out definitions, pre-market pathways, claims frameworks, GMP/quality requirements, and post-market duties. A semi-quantitative scoring rubric allowed structured comparison across five domains: pre-market stringency, claims evidence standards, GMP oversight, post-market vigilance, and ingredient governance. The results of this study highlight the diversity of global regulatory approaches to nutraceuticals and dietary supplements. A clear divide emerges between food-based regimes (e.g., United States, EU, India, Brazil, Japan's FFC) and medicinal-style regimes (Canada, Australia), with China straddling both through its registration vs. filing system. Canada and Australia: Rigorous Medicinal Oversight. Both Canada and Australia adopt a therapeutic goods framework for supplements. Canada requires Natural Health Product (NHP) licensing, while Australia applies a risk-tiered complementary medicines system with "listed," "assessed listed," and "registered" products. These regimes impose: Pre-market licensing (products and sites), Mandatory GMP compliance aligned with pharmaceutical standards (PIC/S GMP in Australia; NHP GMP in Canada), Evidence standards tied to indication risk. Ultimately, a globally harmonized, risk-proportionate framework for nutraceuticals and supplements anchored in safety, quality, and truthful marketing remains both a challenge and an opportunity for regulators, industry, and consumers alike.

Keywords: United States, EU, India, Brazil, Japan's FFC, Natural Health Product (NHP), GMP

Introduction

The pharmaceutical industry operates within a highly regulated environment where the approval of new drug applications (NDAs) represents a critical step in ensuring that innovative therapies reach patients safely, effectively, and in a timely manner. Regulatory frameworks serve as the cornerstone of public health protection by establishing rigorous scientific and legal standards for evaluating the quality, safety, and efficacy of medicinal products before they enter the market. While globalization of drug development has accelerated in recent decades, significant regional variations in approval processes persist, influencing the pace of innovation, patient access, and strategic decision-making for pharmaceutical sponsors.

Nutraceuticals and dietary supplements occupy a fast-growing space at the intersection of food, medicine, and consumer wellness. They include vitamins and minerals, botanicals and herbal preparations, probiotics, amino acids, functional foods and beverages, and a wide array of concentrated bioactive ingredients derived from plants, animals, or microorganisms. Although these products are typically marketed for health maintenance, performance, or disease-risk reduction—rather than diagnosis, treatment, or cure—their regulatory treatment varies substantially across jurisdictions. In some markets they are governed primarily as foods with additional controls; in others they fall under bespoke "natural health product" or "traditional medicine" regimes; and in a few, particular categories are regulated as medicines. This heterogeneity creates complexity for manufacturers, health professionals, and regulators, especially as global supply chains, cross-border e-commerce, and social-media marketing collapse traditional market boundaries.

From a public-health perspective, the core policy challenge is to strike an appropriate balance between access and assurance: enabling consumer choice and innovation while safeguarding quality, safety, and truthful communication about benefits and risks. The policy levers commonly used to achieve this balance—pre-market notification or authorization for certain ingredients, good manufacturing practice (GMP) or equivalent quality systems, adverse-event reporting, labeling and claims standards, and post-market surveillance—are configured differently across regulatory systems. As a result, a product that can be sold as a food supplement in one country may require medicinal authorization in another, or be considered a "novel food" that demands separate pre-clearance. Differences in definitions (e.g., what counts as "supplement," "nutraceutical," "health food," or "traditional herbal medicinal product"), claim categories (structure/function vs. disease-risk reduction vs. therapeutic), and evidentiary expectations (traditional use, observational data, randomized trials) further complicate regulatory convergence. Economically, the sector's expansion has been driven by demographic aging, rising non-communicable diseases, self-care trends, and the wellness industry's emphasis on prevention and performance. The

acceleration of direct-to-consumer channels and personalized nutrition—enabled by digital tools, wearables, and microbiome or genetic testing—has intensified both innovation and regulatory scrutiny. High-profile safety incidents, variability in product quality, and exaggerated or misleading claims have catalyzed reforms in many markets, including stronger GMP requirements, list-based ingredient controls, and clearer advertising standards. Meanwhile, evidence standards are evolving: beyond classical randomized controlled trials, regulators increasingly consider real-world evidence, systematic reviews, and, in traditional medicine pathways, historical usage under defined conditions.

This comparative analysis focuses on the regulatory requirements governing nutraceuticals and dietary supplements in major markets with significant commercial influence and mature oversight frameworks. For the purposes of this report, "major markets" encompass: the United States; the European Union (with attention to both EU-level instruments and member-state implementation nuances); Canada; the United Kingdom (post-Brexit evolution); Australia; Japan; China; and India. Where relevant, we reference regional initiatives (e.g., ASEAN Traditional Medicines and Health Supplements harmonization) to illustrate convergence trends. The term "nutraceutical" is used descriptively in industry and academia but lacks a universally binding legal definition; accordingly, our analysis maps each jurisdiction's legally defined product categories (e.g., "dietary supplements," "food supplements," "natural health products," "listed medicines," "Foods for Specified Health Uses," "health foods") onto the broader concept. Regulatory themes and points of comparison. We structure the comparison around six pillars that most directly shape product development, market access, and lifecycle compliance:

- Product classification and scope. How the law defines eligible products and distinguishes them from conventional foods, fortified foods, medical foods, traditional medicines, and pharmaceuticals; treatment of borderline categories (e.g., high-dose vitamins, concentrated botanicals, probiotics, and novel bioactives).
- Ingredient governance. Positive/negative lists, novel ingredient approval pathways, maximum/minimum levels for vitamins and minerals, and restrictions on certain botanicals, stimulants, or bioactives; recognition of traditional-use monographs or pharmacopeial standards.
- Manufacturing quality and controls. Applicability of GMP or food-grade HACCP systems; testing standards for identity, purity, strength, and contaminants; documentation and batch-release expectations, including for imported products and contract manufacturers.
- Evidence and claims. Permissible claim types (nutrient content, structure/function, general health, disease-risk reduction, therapeutic), pre-market substantiation requirements, and approval or notification processes; advertising and social-media guardrails; substantiation hierarchies (RCTs, systematic reviews, traditional use).
- Market entry and notifications. Need for pre-market notification, listing, registration, or authorization at the product or ingredient level; timelines and the extent of dossier expectations (formulation, labeling, stability, safety, efficacy/evidence summaries).
- Post-market obligations. Adverse event reporting, product traceability and recalls, periodic safety or quality reporting, inspection regimes, and enforcement practices, including penalties for non-compliance or misleading promotion.

Why a comparative approach matters now. Companies increasingly operate multi-region portfolios, reformulating or repositioning products to meet divergent rules. Understanding the "common core" (e.g., identity testing, contaminant limits, truthful non-therapeutic claims) versus jurisdiction-specific requirements (e.g., EU novel food authorization, Japan's FOSHU/FUNC claim regimes, Australia's listed medicines pathway, Canada's NHP licensing, China's health food registrations/notifications, India's nutraceutical standards) enables efficient pipeline design, sourcing, and labeling strategy. For regulators, mapping similarities and divergences highlights where international standards (Codex Alimentarius, pharmacopeias) or mutual reliance could reduce redundancy without diluting consumer protection. For clinicians and consumers, clarity on claims and evidence supports informed decision-making and mitigates risk from substandard or adulterated products.

Scope and boundaries of this report. This review addresses finished products sold for oral consumption (capsules, tablets, powders, liquids, functional foods/beverages) intended for health maintenance or risk-reduction, excluding products that are unequivocally regulated as prescription or over-the-counter medicines. We do, however, discuss "borderline" determinations because they often dictate whether a product can be marketed at all and with what claims. We also consider supply-chain quality controls (e.g., botanical identification, contaminants like heavy metals, pesticides, residual solvents, mycotoxins), given their centrality to safety and regulatory compliance. While we reference traditional medicine frameworks (e.g., Japanese Kampo, EU traditional herbal registrations, India's AYUSH systems) where they directly intersect with supplements, exhaustive coverage of those systems is beyond our primary scope.

Analytical framework and methods. The chapters that follow apply a structured rubric to each jurisdiction: (i) legal definitions and classification; (ii) competent authorities and guidance landscape; (iii) ingredient controls and maximum levels; (iv) pre-market obligations (notification, listing, authorization); (v) manufacturing and quality standards; (vi) labeling, packaging, and claims (including digital marketing); (vii) pharmacovigilance and post-market surveillance; and (viii) enforcement trends and case examples. We integrate statutory instruments, implementing regulations, regulator guidance, monographs, and, where instructive, notable enforcement actions and policy consultations. We complement black-letter requirements with operational considerations—what evidence manufacturers typically compile, where reviewers focus during inspections or dossier assessments, and recurring pain points

(e.g., substantiation of probiotics, setting safe upper limits for botanicals with variable alkaloid profiles, and harmonizing claim language across markets).

Anticipated contributions. This comparative analysis aims to:

- Provide a practical map of regulatory pathways for market access and maintenance across major jurisdictions.
- Clarify how differences in definitions and claims policy affect product positioning and communications strategy.
- Summarize evidence expectations for common claim types, highlighting acceptable study designs and documentation practices.
- Identify areas of emerging convergence (e.g., adverse-event reporting, GMP-like requirements) and persistent divergence (e.g., novel foods, therapeutic claims).
- Offer actionable recommendations for portfolio planning, dossier assembly, supplier qualification, and risk management in multi-market launch scenarios.

Report structure. After this Introduction, Chapter 2 presents a high-level comparative matrix of classification, ingredient controls, claims regimes, and market-entry requirements. Chapters 3–10 provide detailed jurisdictional deep-dives (United States, European Union, United Kingdom, Canada, Australia, Japan, China, and India). Chapter 11 synthesizes cross-cutting themes quality, evidence, digital advertising and highlights recent policy developments and consultation trajectories. Chapter 12 concludes with strategy recommendations for manufacturers and suggestions for regulatory cooperation that preserve consumer protection while reducing unnecessary friction. Suggested figures/tables for this chapter (placeholders):

Materials and Methods

Study Design

This study employed a comparative legal and regulatory **analysis** framework, drawing upon documentary review of primary sources of law (acts, regulations, directives) as well as regulator-issued guidance documents and official agency summaries**.** Supplementary use of secondary analyses (peer-reviewed literature, consultancy reports, and industry position papers) was limited to contextualizing jurisdictions where official English translations are restricted (notably China and Brazil).

Inclusion Criteria

- Temporal scope: Documents in force as of September 2025**.**
- Geographic scope: Eight jurisdictions of interest – United States, European Union, Canada, Australia, India, Japan, China, and Brazil.
- Document type: Statutes, implementing regulations, official directives, agency guidance, FAQ pages, and consolidated legal texts.
- **Competent authorities covered:**
    - FDA (U.S.)
    - EUR-Lex/EFSA (EU)
    - Health Canada
    - Therapeutic Goods Administration (TGA, Australia)
    - FSSAI (India)
    - Consumer Affairs Agency (CAA) / MHLW (Japan)
    - State Administration for Market Regulation (SAMR, China)
    - ANVISA (Brazil)
- **Secondary sources:** Used only where official English-language materials were unavailable or incomplete; all such materials were cross-checked for date and consistency**.**

Data Sources

- **Primary:**
    - Official regulatory portals (e.g., FDA.gov, EUR-Lex, EFSA.europa.eu, Health Canada, TGA.gov.au, FSSAI.gov.in, CAA.go.jp, SAMR.gov.cn, ANVISA.gov.br).
    - Consolidated legal texts (e.g., U.S. Code of Federal Regulations, EU Regulations / Directives, Indian FSSAI compendia).
- **Secondary (contextual):**
    - Credible consultancy white papers (e.g., Deloitte, KPMG, PwC) with transparent citation of primary law.
    - Industry association summaries (e.g., CRN, IADSA) used to triangulate interpretations.

Data Extraction

A **two-layer abstraction template** was used to standardize analysis across markets. Extracted domains included:

1. **Legal definition / category** of product.
2. **Responsible authority** and its role in governance.
3. **Pre-market pathway** (notification, filing, registration, licensing).
4. Permitted ingredients / positive lists (including maximum/minimum levels).
5. **Claims taxonomy** (nutrient content, structure/function, health, disease risk-reduction) and corresponding **evidence standards**.
6. **GMP / quality and site controls** (including audits, inspections, import requirements).
7. **Labeling / disclaimer obligations**, including digital marketing rules.
8. **Post-market duties**, e.g., adverse event reporting (AER), recalls, pharmacovigilance-like systems.

Comparative Scoring Framework

A semi-quantitative rubric was developed to enable structured comparison across domains. Each jurisdiction was assigned a **0–**3 **score** per domain:

- 0 = Absent or minimal regulatory control
- 1 = Basic requirements with limited prescriptiveness
- 2 = Moderate requirements; some pre-market controls or standardized evidence expectations
- 3 = Highly prescriptive; robust pre-market evaluation, strong GMP, rigorous post-market surveillance

Domains scored:

1. Pre-market stringency
2. Claims evidence bar
3. GMP and manufacturing oversight

4. Post-market reporting and enforcement
5. Ingredient controls

This allowed creation of heatmaps and radar plots to visualize regulatory intensity and highlight areas of convergence or divergence.

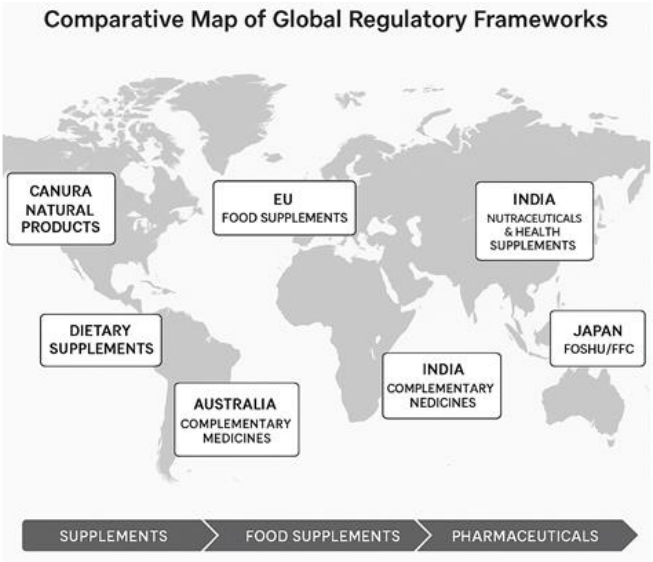

Fig.1: Comparative Map of Global Regulatory Framework

Limitations

- **Regulatory change lag:** Rapid policy shifts (e.g., **China's evolving labeling standards**, **EU maximum nutrient levels**) may not be fully captured in English-language updates at the time of review.
- **Jurisdictional variability:**
  - Within the **EU**, implementation varies across Member States, particularly regarding maximum nutrient levels and notification procedures.
  - Federal systems (e.g., **U.S., Canada, Brazil**) allow for state/province-level nuances beyond national statutes.
- **Scope constraint:** Focus limited to supplements and nutraceuticals, excluding **traditional medicines** unless directly regulated under supplement law.
- **Non-legal advisory:** This analysis synthesizes legal/regulatory texts for academic purposes; it does not constitute legal advice.

Table 1: Comparative Scoring Rubric

Domain	Score 0	Score 1	Score 2	Score 3
Pre-market	No pathway	Notification only	Filing/limited review	Full registration/licensing
Claims evidence	No requirement	Basic substantiation	EFSA-like dossier	Rigorous RCT + regulator approval
GMP	None	Food GMP	Supplement GMP	Pharma-grade GMP (PIC/S)
Post-market	None	Voluntary reporting	Mandatory AER	Mandatory AER + active surveillance
Ingredient controls	None	General food rules	Positive/negative lists	Detailed monographs + upper limits

Result and Discussion

Comparative Overview (Narrative)

Classification & Scope

Across most jurisdictions, nutraceuticals, dietary supplements are regulated as foods with special regimes (e.g., United States, European Union, India, Japan's FFC system, Brazil). In contrast, Canada and Australia apply medicinal-style frameworks Canada through Natural Health Products (NHPs) and Australia through Complementary Medicines—requiring pre-market authorizations and licensing. This fundamental divide between food-based and therapeutic-style oversight strongly shapes all subsequent requirements.

Market Entry Pathways

The **United States** relies on post-market control, with limited pre-market intervention except for New Dietary Ingredient (NDI) notifications. The EU applies notification requirements alongside harmonized vitamin/mineral lists, though Member State differences persist. Canada and Australia demand pre-market licensing or listing**,** reflecting their risk-based medicinal orientation. **India** mandates registration/licensing under defined FSSAI categories, while Japan distinguishes between government-approved (FOSHU) and company-notified (FFC) systems. China operates a dual-track system of registration versus filing**,** Brazil applies category-specific notification/authorization under RDC frameworks.

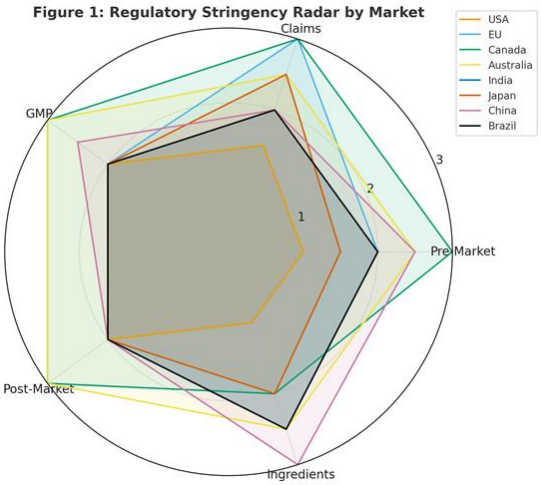

Figure 2: Regulatory Stringency Radar by Market

Ingredient Controls

Ingredient regulation is highly list-driven in most jurisdictions:

- **EU** — Positive lists for vitamins/minerals.
- **India** — Ingredient schedules.
- **Australia** — Permitted ingredient list.
- **China** — Health food catalogs.
- **Brazil** — RDC ingredient lists. By contrast, the **U.S.** applies a broader definition, with pre-market scrutiny triggered only for **new dietary ingredients**.

Claims and Evidence

- EU**:** Only EFSA-assessed claims are allowed.
- U.S.**:** Structure/function claims permitted with disclaimers; qualified health claims require FDA petition.

- Canada & Australia: Evidence standards proportional to risk; higher claims require more robust dossiers.
- Japan**:** FOSHU approvals demand government review, while FFC claims rely on company evidence with strict labeling.
- India/Brazil**:** Permitted claim lists; therapeutic/disease-treatment claims prohibited.
- China**:** Restricts claims to functional categories in official catalogues.

GMP and Quality Standards

- **U.S.**: 21 CFR Part 111 (dietary supplement GMP).
- **Canada**: NHP GMP with site licensing.
- **Australia**: PIC/S GMP for listed/registered medicines.
- **India**: FSSAI standards with references to additive/contaminant controls.
- **EU**: Food GMP/HACCP.
- **China**: Manufacturing license with mandatory testing.
- **Brazil**: Food GMP with compendial references.

Post-Market Obligations

All jurisdictions maintain recall powers. Mandatory serious AER reporting exists in the U.S., Canada, and Australia, while India, China, and Brazil are strengthening surveillance mechanisms. The EU coordinates alerts through systems like RASFF/RAPEX.

Table 2: Legal Classification & Competent Authority

Market	Legal Category	Primary Authority
United States	Dietary supplement (food category)	FDA – Human Foods Program; Office of Dietary Supplement Programs
European Union	Food supplement (food law)	European Commission / Member States; EFSA for claims
Canada	Natural Health Product (medicinal)	Health Canada – NNHPD
Australia	Complementary medicine (listed/registered)	Therapeutic Goods Administration (TGA)
India	Health supplements, nutraceuticals, FSDU, FSMP, Pre/Probiotics	Food Safety and Standards Authority of India (FSSAI)
Japan	FOSHU / FFC / FNFC (food claims systems)	Consumer Affairs Agency (CAA); MHLW
China	Health Food (registration/filing)	State Administration for Market Regulation (SAMR)
Brazil	Suplemento alimentar	ANVISA

Table 3: Market Entry Pathways

Market	Entry Route
United States	No routine pre-market approval; NDI notification for new ingredients
European Union	Member State notification; novel food authorization for new substances
Canada	Pre-market product license (NPN) + site license
Australia	AUST L (self-certified listed); AUST L(A) (assessed listed); AUST R (registered)
India	Licensing/registration under FSSAI categories; compliance with schedules
Japan	FOSHU approval (government reviewed); FFC notification; FNFC standard claims
China	Registration (novel/functional); filing (catalog vitamins/minerals)
Brazil	Category-specific notification/authorization per RDC lists

Table 4: Claims & Evidence

Market	Claims Regime	Evidence Standard / Notes
USA	Structure/function, nutrient content, qualified health claims	Substantiation required; S/F disclaimer; QHC via FDA petition
EU	Nutrition/health claims (Articles 13/14)	EFSA scientific assessment; only authorized claims allowed
Canada	Claims tied to NPN license	Evidence proportional to risk; monographs streamline low-risk claims
Australia	AUST L permitted indications; AUST R/L(A) higher claims	Dossiers required; TGA compliance reviews
India	Permitted claims lists; no disease treatment claims	Evidence per FSSAI schedules; label warnings
Japan	FOSHU approved; FFC notified with dossier; FNFC standardized	Clinical/systematic evidence for FFC; precise label language
China	Catalog-limited functional claims	Technical dossier for registration; filing for vitamins/minerals
Brazil	Claims lists; therapeutic claims prohibited	RDC 241/243; IN 28 defines ingredient/claim limits

Table 5: GMP/Quality & Post-Market

Market	GMP / Quality	Post-Market Duties
USA	21 CFR Part 111 (cGMP)	Mandatory serious AERs; inspections; recalls
EU	Food GMP/HACCP; Member State enforcement	Surveillance; RASFF/RAPEX alerts; recalls
Canada	NHP GMP; site licensing	AERs; recalls; inspections
Australia	PIC/S GMP	Mandatory AERs; post-market reviews
India	FSSAI quality standards; additive/contaminant controls	Recalls; label checks; evolving AER reporting
Japan	Food GMP + dossier standards	Post-market monitoring; audits
China	Manufacturing license + testing	Label checks; AERs; license renewal
Brazil	Food GMP; compendial references	Market monitoring; AERs; recalls

Discussion

This study undertook a comparative regulatory analysis of nutraceuticals and dietary supplements across eight major markets: United States, European Union, Canada, Australia, India, Japan, China, and Brazil**.** Through systematic review of legal texts, guidance documents, and regulator portals, the research mapped out definitions, pre-market pathways, claims frameworks, GMP/quality requirements, and post-market duties**.** A semi-quantitative scoring rubric allowed structured comparison across five domains: pre-market stringency, claims evidence standards, GMP oversight, post-market vigilance, and ingredient governance.

The key findings may be summarized as follows:

Classification and Scope

- Most jurisdictions regulate supplements as foods with special rules (U.S., EU, India, Japan's FFC, Brazil).
- Canada and Australia apply medicinal-style regimes requiring pre-market authorizations.

- Hybrid systems (India, Japan, China, Brazil) balance ingredient lists, notifications, and approvals**.**

Market Entry Pathways

- **USA:** Minimal pre-market intervention (NDI notification).
- **EU:** Member State notification plus novel food authorization.
- **Canada/Australia:** Licensing or listing with evidence review.
- **India/China:** Category-specific licensing or filing/registration.
- **Japan:** Dual approval (FOSHU) and notification (FFC).
- **Brazil:** Category-specific notifications under ANVISA rules.

Claims and Evidence

- **EU:** EFSA-authorized claims only.
- **USA:** Structure/function claims allowed with disclaimers; qualified claims via petition.
- **Canada/Australia:** Evidence proportional to risk, supported by monographs.
- Japan: FOSHU (approved) vs FFC (notified with company evidence).
- India/China/Brazil: Positive claim lists; prohibition of therapeutic claims.

GMP and Quality

- Canada/Australia: Pharmaceutical-grade GMP standards (PIC/S).
- USA: Supplement GMP (21 CFR 111).
- EU: Food GMP/HACCP.
- China/India/Brazil: Food GMP plus catalog/list-based ingredient controls.

Post-Market Surveillance

- U.S., Canada, Australia: Mandatory **serious** adverse event reporting (AERs)**.**
- EU: Coordinated surveillance through RASFF/RAPEX.
- India, China, Brazil, Japan: Emerging or strengthening AER/recall frameworks.

Cross-Cutting Themes

- **Convergence:** Prohibition of disease claims, baseline GMP requirements, and universal recall powers.
- **Divergence:** Authorization of claims, scope of positive lists, and intensity of pre-market review.
- **Policy levers for harmonization:** Positive list expansion, mutual recognition of evidence monographs, interoperable AER systems, and tiered claims models.

Policy Implications

The study identifies clear opportunities for regulators:

- **Short-term:** Bilateral recognition of evidence standards and ingredient lists.
- **Medium-term:** Regional harmonization (e.g., ASEAN, Codex-driven approaches).
- **Long-term:** Development of interoperable AER databases, digital market surveillance frameworks, and globally accepted claim tiers.

For industry, strategies include:

- Building **adaptable claims banks** spanning EU, U.S., and Asia-Pacific.
- Planning licensing timelines for Canada/Australia.
- Tracking ingredient catalog updates in India/China.
- Implementing global GMP systems above the strictest baseline (PIC/S).

Limitations

This study faced constraints due to rapid regulatory evolution (e.g., China's labeling rules, EU maximum levels), federal/ multi-state variations (e.g., U.S., EU, Brazil), and limited publicly available AER/recall datasets**.** Furthermore, it excludes in-depth treatment of traditional medicine systems unless they intersect directly with supplement law**.**

Conclusion

The global nutraceutical and dietary supplement sector is expanding rapidly, but regulatory heterogeneity remains a defining challenge. Jurisdictions balance access, innovation, and consumer protection differently: the U.S. prioritizes innovation with post-market control; the EU prioritizes truth in labeling through claims assessment; Canada and Australia emphasize risk-based medicinal oversight; and emerging markets (India, China, Brazil, Japan) pursue hybrid list-based regimes. Despite divergences, there are converging threads notably in claim prohibitions, GMP adoption, and recall systems that offer pathways toward gradual alignment. Building mutual recognition systems, shared data standards, and interoperable catalogs could reduce duplication, enhance compliance, and foster responsible innovation. Ultimately, a globally harmonized, risk-proportionate framework for nutraceuticals and supplements anchored in safety, quality, and truthful marketing remains both a challenge and an opportunity for regulators, industry, and consumers alike.

Conflict of Interests

The authors declare no conflict of interest

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AI Tool Declaration

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

Data Availability

Data will be available on request

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